PART IV

ECOLOGICAL RISK ASSESSMENT

Chapter 23 Overview and Getting Started: Problem Formulation

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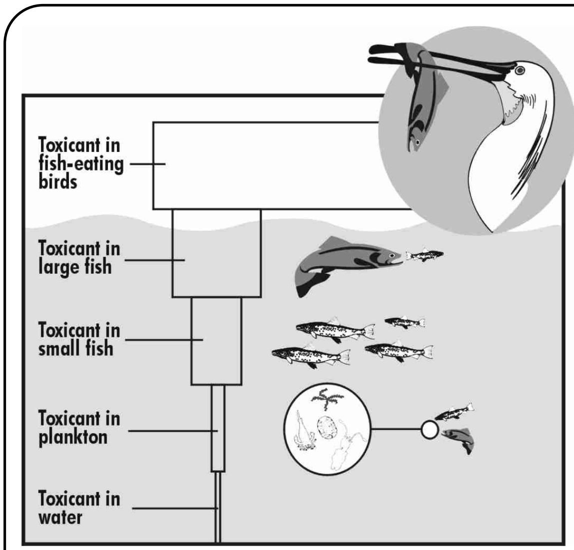
23.1 Introduction

Part IV constitutes a snapshot of EPA's current thinking and approach to the adaptation of the evolving methods of ecological risk assessment to the context of Federal and state control of air toxics. While inhalation risk assessment has been increasingly used in regulatory contexts over the last several years, ecological risk assessment tools are less well developed and field tested in a regulatory context. Part IV should be considered a living document for review and input. By publishing Part IV in its current state of development, EPA is soliciting the involvement of persons with experience in this field to help improve these assessment methods for use in a regulatory context. EPA anticipates revisions to this draft section of Part IV on the basis of this input.

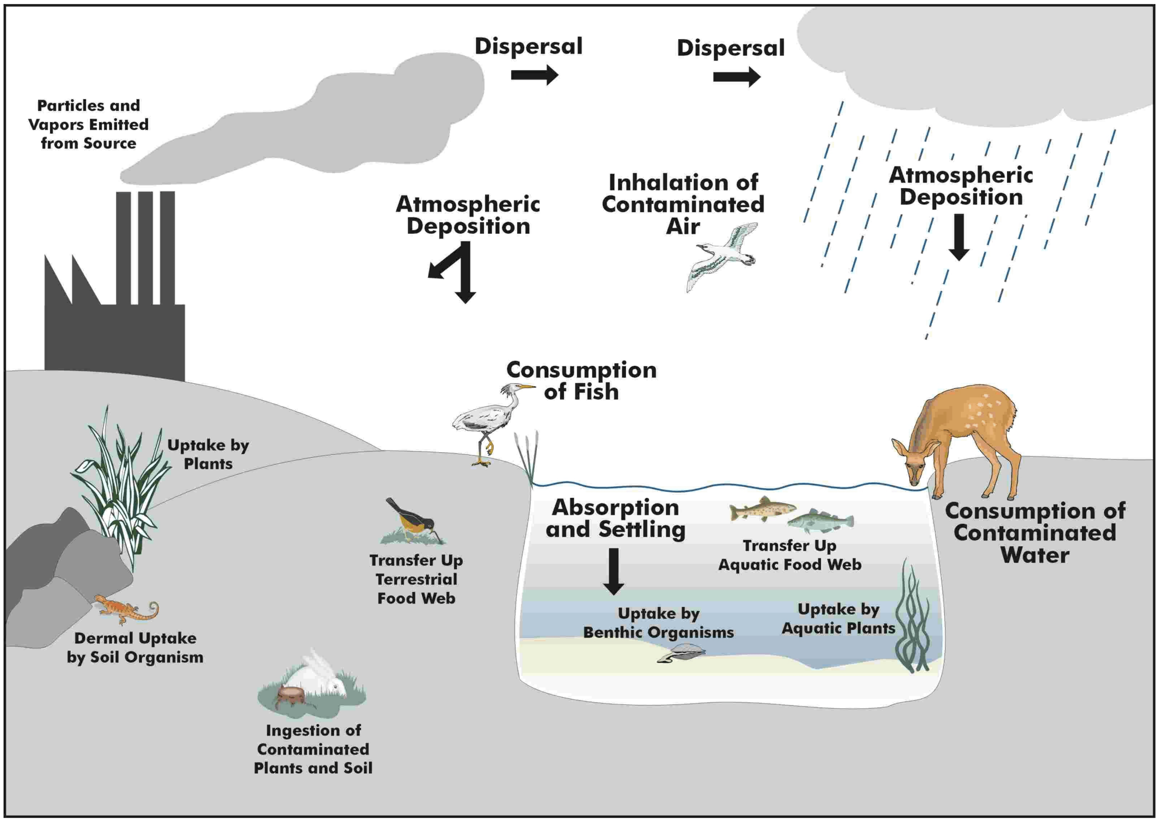
Part III of this Reference Manual discusses how to plan for and conduct a multipathway human health risk assessment when air toxics that persist and may also bioaccumulate (e.g., the persistent bioaccumulative hazardous air pollutant compounds, or PB-HAPs) in media other than air and/or biomagnify in food chains are present in releases. For these compounds, the risk assessment generally will need to include consideration of exposure pathways that involve deposition of air toxics onto soil and plants and into water, subsequent uptake by biota, and potential human exposures via consumption of contaminated soils, sediments, surface waters, and foods. These substances may also pose risks to ecological receptors from direct exposure to contaminated media or through indirect exposure via aquatic and terrestrial food chains (see Exhibit 23-1). The preliminary list of PB-HAPs was derived primarily on the basis of exposure and risk/hazard once HAPs are deposited onto soils, into surface waters, etc. Its derivation did not consider direct exposures of ecological receptors to air toxics while they are in the air (e.g., phytotoxic effects on plants; inhalation by animals). Additional HAPs of potential concern for ecological risk may be identified as EPA gains more familiarity with ecological risk assessments for air toxics. Appendix D describes the process by which EPA identified the PB-HAP compounds.



Trophic Levels and Biomagnification

The trophic level is a way to describe where an organism may be located within an aquatic or terrestrial food web. The lowest trophic level consists of primary producers, the green plants that convert sunlight into carbohydrates via photosynthesis. The next trophic level generally consists of primary consumers, or the organisms that feed directly on green plants. The next level up, often termed secondary consumers, represents animals that feed on primary consumers. The highest trophic level consists of the top predators in the food web. For some chemicals, the concentration in biological tissue can increase as it moves up the food chain, a process called **biomagnification**.

Exhibit 23-1. Air Toxics Exposure Pathways of Potential Concern for Ecological Receptors



This graphic illustrates some of the potential multimedia pathways of concern for air toxics exposure to ecological receptors. Air toxics released from a source disperse through the air and eventually fall to the earth (atmospheric deposition) via settling and/or precipitation. Air toxics deposited to soil may be absorbed or ingested by plants and soil invertebrates (uptake). Terrestrial animals may be exposed to air toxics via ingestion of contaminated plants and soil, or by consuming contaminated terrestrial animals (for those air toxics that bioaccumulate and transfer up the terrestrial food web). Air toxics deposited to water may be dissolved in the water column and/or may settle and be absorbed into aquatic sediments. Air toxics in sediments may be absorbed or ingested by benthic organisms (uptake); those in sediments and the water column may be absorbed by aquatic plants (uptake). Aquatic organisms (e.g., fish) may be exposed directly to air toxics in the water column and/or by consuming contaminated aquatic organisms (for those air toxics that bioaccumulate and transfer up the aquatic food web). Terrestrial animals may be exposed to air toxics by eating contaminated fish or shellfish and/or by drinking contaminated water. Note also that, while in the atmosphere, air toxics may also have direct impacts on plants (direct exposure) and terrestrial animals (inhalation).

This part (Part IV) of this reference manual introduces the basic concepts of ecological risk assessment and describes their application to air toxics. Several differences of particular importance are highlighted in a text box on page 23-3. The discussion of ecological risk assessment follows the same general framework as that presented in Part III since the overall concept is the same; namely that certain air toxics may move from the air into other media where exposures to organisms (in this case, non-human organisms) can occur with potentially adverse outcomes. Readers are strongly encouraged to become familiar with the information provided in Part III before reading this Part. ***However, although there are many similarities between***

multimedia human health risk assessment and ecological risk assessment (e.g., they may use the same multimedia monitoring and modeling tools), professional expertise will always be required to apply the ecological risk assessment principles and tools identified in this document to specific assessment areas or problems. This document is not a substitute for a working familiarity with ecological principles, their application, and the field of ecological risk assessment.

> ***Air toxics may have adverse effects on ecological receptors through direct exposures (e.g., inhalation by animals; direct deposition onto plants). However, EPA does not have sufficient experience with multipathway air toxics risk assessments to identify the circumstances for which these exposures would represent a potential concern. This reference manual therefore does not address these additional exposure pathways. The methods for conducting such an analysis are described in greater detail in EPA's Guidelines for Ecological Risk Assessment.***[1]

This chapter presents an overview of ecological risk assessment and discusses the initial planning and scoping activities. The remaining chapters of this part focus on Characterization of Exposure (Chapter 24), Characterization of Ecological Effects (Chapter 25), and Risk Characterization (Chapter 26). The discussion presented here is based largely on EPA's *Guidelines for Ecological Risk Assessment*[1] and the *Residual Risk Report to Congress.*[2] The *Guidelines for Ecological Risk Assessment* were developed especially for evaluating ecological risk. Readers are also strongly encouraged to become familiar with that document for a more complete understanding of EPA's recommended approach to ecological risk assessment. Interested readers are also referred to *EPA's Ecological Risk and Decision Making Workshop* materials which provide detailed information on the definition of ecological risk assessment, how it relates to human health assessment, the ecosystem protection place-based approach, and the bases for ecological protection and risk assessment at EPA.[3]

Key Ecological Risk Assessment Resources

- NCEA's Ecological Risk Assessment webpage http://cfpub.epa.gov/ncea/cfm/ecologic.cfm
- The Oak Ridge National Laboratory Ecological Risk Assessment webpage on tools, guidance, and applications http://www.esd.ornl.gov/programs/ecorisk/ecorisk.html
- The Superfund Ecological Risk Assessment Program http://epa.gov/superfund/programs/risk/ecolgc.htm
- Navy Guidance for Conducting Ecological Risk Assessments http://web.ead.anl.gov/ecorisk/
- EPA's Watershed Ecological Risk Assessment program http://cfpub.epa.gov/ncea/cfm/weracs.cfm?ActType=default

Some Important Differences Between Ecological Risk Assessment and Multipathway Human Health Risk Assessment

- **Planning and scoping**. The ecological risk assessment requires more preliminary analysis and deliberation regarding endpoints to be assessed and toxicity reference values to be used because ecological systems are more complex and are not as well understood biologically as human health systems. The planning and scoping team should include individuals with specific expertise in ecological risk assessment.

- **Assessment area**. It may be necessary to evaluate additional portions of the assessment area that are not of concern from a human health perspective.

- **Potentially exposed populations**. The focus shifts from potentially exposed individual humans to potentially exposed populations and species of ecological receptors of concern. In many cases, the exposure assessment may need to address multiple species and life-stages, many of which have physiological and biochemical processes that differ significantly from humans. (When threatened or endangered species are present, the assessment may also include an evaluation of those organisms as individuals).

- **Exposure pathways and exposure routes**. It may be necessary to assess different exposure pathways and routes that are not of concern for human health.

- **Ecological effects assessment**. Ecological systems have traits and properties that are different from humans and, thus, the ecological effects assessment (comparable to hazard assessment for human health) may consider a wider range of potential causal relationships.

- **Risk characterization**. While risks may be assessed at multiple levels of ecological organization (i.e., organism, population, community, and ecosystem), they generally are assessed at the population level in air toxics assessments. (Nevertheless, when appropriate, consideration should be given to assessments at high levels of ecological organization, such as at the landscape level).

23.2 Overview of Air Toxics Ecological Risk Assessment

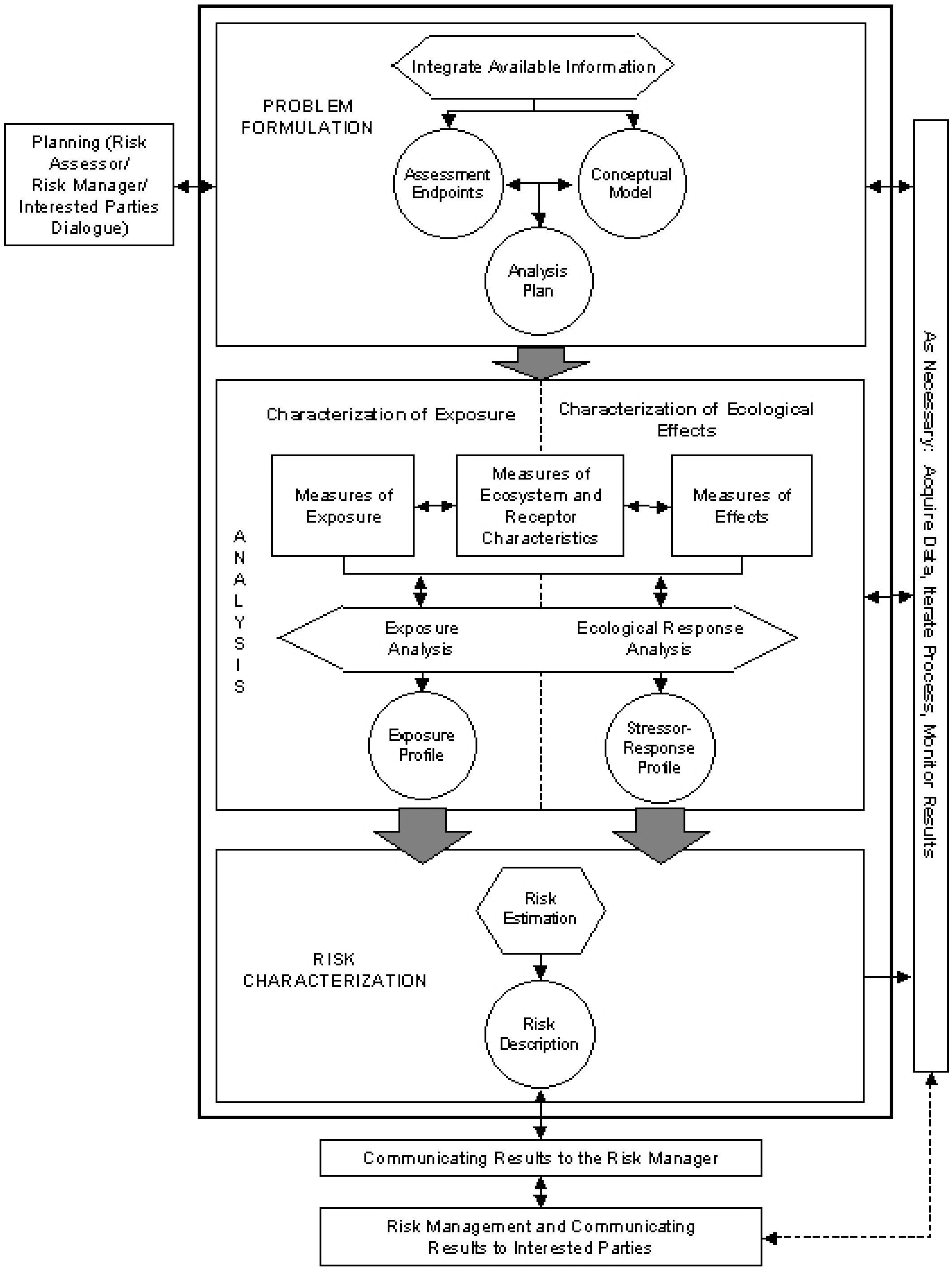
The ecological risk assessment process has three main steps that broadly correspond to the four basic steps in human health risk assessment methodology (Exhibit 23-2):[1]

- **Problem formulation**, which corresponds to the problem formulation step of the human health risk assessment methodology (planning and scoping activities similar to human health risk assessment are also integrated with this step; however, they are discussed separately below to maintain the operational structure of the ecological risk assessment as described in EPA's ecological risk assessment guidelines);

- **Analysis**, which corresponds to the exposure assessment and toxicity assessment steps of the human health risk assessment methodology; and

- **Risk characterization**, which corresponds to the risk characterization step of the human health risk assessment methodology.

Exhibit 23-2. Ecological Risk Assessment Framework



Source: EPA Guidelines for Ecological Risk Assessment[1]

23.2.1 Problem Formulation

Problem formulation provides the foundation for the entire ecological risk assessment. This step includes:

- Identifying risk management goals from an ecological perspective, ecological receptors of concern (e.g., wetlands, fish populations, keystone species that impact the overall ecosystem), and assessment endpoints (explicit expression of the environmental value that is to be protected, operationally defined by an ecological entity and its attributes);

- Developing the ecological risk part of the conceptual model as necessary to account for ecological exposure pathways and receptors; and

- If necessary, developing the Sampling and Analysis Plan and associated Quality Assurance Project Plan to collect data on exposures and measures of effects that are needed to support the ecological risk assessment.

As with human health risk assessments, problem formulation is often an iterative process, in which substantial re-evaluation may occur as new information and data become available. Data collection in subsequent iterations often is triggered by identification of major data gaps and uncertainties in the risk characterization that prevent confident decision-making by risk managers.

The problem formulation process for ecological risk assessment for air toxics focuses on developing a common understanding of what needs to be done to assess *ecological* risks associated with pathways involving deposition; the transfer of compounds to soil, water, sediment, and biota, and subsequent exposure. While the ecological risk assessment may build on the foundation of the human health multipathway assessment (e.g., using the same emissions data and multimedia models), the problem formulation step is particularly critical for the ecological risk assessment because of the effort needed to understand and identify ecological receptors, exposure pathways, endpoints, and management goals. The ecological risk assessment is not simply an "add-on" to the human health multipathway risk assessment. The problem formulation effort will need to consider a wide variety of possible ecological receptors that are not similar to humans. For example:

- Different species (and life stages) may have very different responses to the same exposure. Therefore, knowledge of the exposure-response of many species, including those that may be particularly sensitive to the air toxic, is needed.

- Ecosystems may show adverse effects at lower exposures than most individual species do because species that are important in terms of ecosystem function (e.g., energy flow, nutrient recycling) may also be sensitive to toxic effects. Ecosystem-level metrics such as species diversity indices may be more sensitive indicators of adverse effects than are toxicological studies.

- There may be many different types of ecosystems present in the assessment area, and sensitivity likely varies among them. Therefore, the particular features of the ecosystem(s) that occur in areas where high exposures are predicted may be particularly important.

An Ecological Risk Assessment Case Study: Ozone Risks To Agroecosystems

The case study summarized here provides an example of how EPA has assessed environmental risks from an air pollutant (ozone) as part of EPA's effort to promulgate National Ambient Air Quality Standards (NAAQS) for criteria air pollutants (see Chapter 2). Note that this example is for ozone, a criteria air pollutant; however, the concepts presented here are relevant to air toxics risk assessment. In addition, an agroecosystem, such as the system discussed here, is more of a human construct than a natural ecosystem and is provided here only for illustration of general principles. An actual air toxics ecological risk assessment of a natural system would have to consider site-specific characteristics of the system in question.

Problem Formulation. Pursuant to the Clean Air Act (CAA), EPA is required to set NAAQS for "any pollutant which, if present in the air, may reasonably be anticipated to endanger public health or welfare and whose presence in the air results from numerous or diverse mobile and/or stationary sources." EPA develops public health (primary) and welfare (secondary) NAAQS. According to section 302 of the CAA, the term welfare "includes ... effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values ...." A secondary standard, as defined in section 109(b)(2) of the CAA, must "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air."

This case study focuses on an assessment endpoint for agricultural crops (e.g., the prevention of an economically adverse reduction in crop yields). Yield loss is defined as an impairment of, or decrease in, the value of the intended use of the plant. This concept includes a decrease in the weight of the marketable plant organ, reduction in aesthetic values, changes in crop quality, and/or occurrence of foliar injury when foliage is the marketable part of the plant. These types of yield loss can be directly measured as changes in crop growth, foliar injury, or productivity, so they also serve as the measures of effect for the assessment.

Exposure Analysis. EPA used ambient ozone monitoring data across the U.S. and a Geographic Information System (GIS) model to project national cumulative, seasonal ozone for the maximum three month period during the summer ozone season. This allowed EPA to project ozone concentrations for some rural parts of the country where no monitoring data were available but where crops were grown, and to estimate the attainment of alternative NAAQS scenarios. The U.S. Department of Agriculture's (USDA's) national crop inventory data were used to identify where ozone-sensitive crop species were being grown and in what quantities. This information allowed the Agency to estimate the extent of exposure of ozone-sensitive species under the different scenarios.

Ecological Effects Analysis. Stressor-response profiles describing the relationship between ozone and growth and productivity for 15 crop species representative of major production crops in the U.S. (e.g., crops that are economically valuable to the U.S., of regional importance, and representative of a number of crop types) had already been developed from field studies conducted from 1980 to 1986 under the National Crop Loss Assessment Network (NCLAN) program. The NCLAN studies also included secondary stressors (e.g., low soil moisture and co-exposure with other pollutants like sulfur dioxide), which helped EPA interpret the environmental effects data for ozone.

Risk Characterization. Under the different NAAQS scenarios, the Agency estimated the increased protection from ozone-related effects on vegetation associated with attainment of the different NAAQS scenarios. Monetized estimates of increased protection associated with several alternative standards for economically important crops were also developed. This analysis focused on ozone effects on vegetation since these public welfare effects are of most concern at ozone concentrations typically occurring in the U.S. By affecting commercial crops and natural vegetation, ozone may also indirectly affect natural ecosystem components such as soils, water, animals, and wildlife.

Source: U.S. Environmental Protection Agency. 1999. *Residual Risk Report to Congress*. Office of Air Quality Planning and Standards, Research Triangle, NC, March 1999. EPA-453/R-99-011.

23.2.2 Analysis

Analysis includes two principal steps. **Characterization of exposures** includes identifying the **contaminants of potential ecological concern** (COPECs) that may affect ecological receptors, characterizing the spatial and/or temporal pattern of stressor concentrations in environmental media (including certain body burden levels), and analyzing the level of contact or co-occurrence (exposure) between the stressors and the ecological receptors. This often is done using the multimedia models identified in Chapter 18; however, different models or approaches may be appropriate. **Characterization of ecological effects** includes identifying the types of effects that different stressors may have on ecological receptors, along with characterizing the **stressor-response relationship** (the relationship between the level of exposure to the stressor and the expected biological or ecological response). A common result is the identification of **ecological toxicity reference values (TRVs)**, which are concentrations of chemicals in environmental media (including biota such as fish tissues) below which no significant ecological effects are anticipated. TRVs are similar, in concept, to RfDs (reference doses) and RfCs (reference concentrations) for human health noncancer evaluations. TRVs may be screening level (i.e., conservative, generic values) or more refined values for use in higher levels of analysis. They may be point values, ranges, or developed using more advanced probabilistic methods (such as Monte Carlo techniques). The ecological exposure characterization also is likely to differ significantly from the corresponding multipathway exposure assessment for human health. For example:

- In addition to food chain (ingestion) exposures, many ecological receptors can be exposed to air toxics via direct contact with contaminated soils (e.g., earthworms) or sediments (e.g., sediment-dwelling invertebrates, bottom-feeding fish); direct exposure to surface water (e.g., free-swimming invertebrates and fish); or direct exposure to contaminated air via inhalation (e.g., birds), dermal contact (e.g., amphibians), deposition to plant surfaces, etc.

- Particular geographic areas of concern may differ because ecological receptors may occur in areas rarely used by human populations (e.g., large wetland areas, ponds where people rarely fish).

- Sampling and analysis may involve a wider range of media (e.g., sediment) and different types of biota (e.g., earthworms, aquatic invertebrates). Each type of sampling and analysis has its own methods, protocols, and Quality Assurance/Quality Control (QA/QC) procedures.

- Quantitative metrics of exposure may include both direct and indirect exposures for ecological receptors. Quantification of direct exposure is similar to human health inhalation analyses, in which ambient concentrations of COPECs in soil, water, and/or sediment are compared to corresponding TRVs. Quantification of indirect exposure via ingestion is similar to that for human health ingestion analyses, except that different food items may be involved, and the appropriate ecological **exposure factors** (e.g., diet, body weight) will be different. As with human health analyses, many exposure factors can be treated either as constants or as distributions in the exposure assessment. Ecological exposure assessments for ingestion pathways frequently use bioenergetic models to more explicitly relate intake to adverse effects.[4]

23.2.3 Evaluation of Ecological Effects

The characterization of ecological effects is similar to a toxicity assessment for human health. It considers the types of adverse effects associated with chemical exposures, stressor-response relationships, and related uncertainties. There are two primary differences:

- Adverse effects of concern generally focus at the population, community, or ecosystem level. With rare exceptions (e.g., threatened or endangered species), effects to individual organisms are not the primary concern. Note, however, that ecological risk assessments often use estimates of impacts to individual organisms (e.g., mortality, reproductive effects) to infer impacts at higher levels of organization because exposure-response data for populations, communities, or ecosystems often are lacking. Some approaches are available, however, for incorporating population-level analysis in ecological risk assessments.[5]

- A distinction is made between **assessment endpoints**, which are the environmental values to be protected, and **measures of effects**, which are the specific measures used to evaluate risk to the assessment endpoints (assessment endpoints and measures of effects are defined in Section 23.3.4.2).

23.2.4 Ecological Risk Characterization

Similar to human health risk characterization, ecological risk characterization combines information concerning exposure to chemicals with information regarding effects of chemicals to estimate risks. Human health risk assessments consider health effects in the bodies of individual people. Ecological risk assessments consider various "health" issues that can range from actual health effects in the bodies of individual ecological receptors to something more attuned to the "health" of the ecosystem as measured by species richness and diversity.

23.3 Planning and Scoping

To ensure that the ecological risk assessment will provide information useful to the risk managers who will be making the risk management decisions, EPA's *Guidelines for Ecological Risk Assessment* recommends a planning and scoping dialogue occur between the risk assessors, risk managers, and where appropriate, interested stakeholders at the very start of the risk assessment process. The outcome of the planning and scoping phase is an agreement on the basic goals, scope, and timing of the risk assessment. Important goals of the dialogue are the identification of the risk management goals and risk management options that the risk assessment will be designed to inform (see accompanying text box). This 'kick-off' dialogue sets the stage for the problem formulation phase, when the plans for the ecological risk assessment are finalized.

Planning and Scoping the Ecological Risk Assessment

The planning phase is complete when agreements are reached on:

- The management goals for ecological values;
- The range of management options the risk assessment is to support;
- Objectives for the risk assessment, including criteria for success; and
- The focus and scope of the assessment, and resource availability.

When actually performing the problem formulation phase of an ecological risk assessment, the five-step planning and scoping process identified for human health risk assessments is a helpful tool to get the right people involved and the risk questions, expectations, and plans in place to make the overall assessment go smoothly and in a scientifically responsible manner. Similar to the human health evaluation process, the risk assessment and management team should be assembled to start identifying the concern, identifying who needs to be involved in the risk assessment process, determining the scope of the risk assessment, describing why there may be a problem, and determining how the concern will be evaluated.

23.3.1 What is the Concern?

In human health risk assessment and risk management, the assessors are dealing with a single organism (human beings) and the precedent and rationale for specific risk management goals (such as the $1x10^{-6}$ to $1x10^{-4}$ cancer risk range) are generally well established. The parallel process for ecosystems, however, is not as easy to study or as straightforward to manage. To begin with, it can be difficult to choose which of many organisms in a study area to evaluate. Moreover, there is little agreement on which (if any) organisms or ecosystems are important enough to single out for protection. These factors make planning, evaluation, and management of ecological risks more complicated and time-consuming (and often, more controversial).

EPA's Risk Assessment Forum developed draft guidance(6) to help decision-makers work with risk assessors, stakeholders, and other analysts to plan for ecological risk assessments that will effectively inform the decisions they need to make. Planning for ecological risk assessment includes three primary steps:

1. **Defining the risk management decision to be made, the context in which it will be made, and its purpose**. This includes articulating the decision or problem that the risk manager faces, understanding the social and legal context for the decision, placing preliminary boundaries on the scope of the risk assessment, and identifying who needs to be involved. Appropriately framing the context will help ensure that management objectives are relevant to the risk manager's decision and increase the likelihood that the information generated by the risk assessment will be useful.

2. **Developing objectives**. This starts with a clear statement of the problem, issue, or opportunity identified in the first step and ends with a set of specific objectives which will guide all of the remaining steps. An important determination is the "what to protect" (i.e., the assessment endpoint) question for ecological issues and to describe what is at stake. Key questions include:
   - What should be protected? Define the entities, ecological processes, and geographic areas to be considered.
   - How is "protection" defined? Define the ecological objectives.
   - What are the most important objectives and how can they be achieved? Review and structure objectives.

   In some cases, there is a strong consensus on "what to protect" (e.g., if a commercially important resource such as a fishery is potentially exposed). In many other cases, it is not always obvious to a risk manager or the public what features of an ecosystem are of potential concern or what the broader consequences would be from adverse effects to those features.

Developing a consensus on the specific risk management objectives may be a difficult and time-consuming part of the planning and scoping process.

3. **Identifying what information is needed to inform the decision**. When identifying information needs, planners are encouraged to think ahead about everything that will be needed to decide what to do about identified risks. Ecological risk is part of the picture, but issues such as feasibility, practicability, cost, and acceptability also need to be factored into the decision. They should also consider who and what resources are available to perform the ecological risk assessment. The aim of this step is to narrow down which questions the risk assessment should address and identify those that will be addressed elsewhere.

The questions identified at this step will be examined during the remainder of the problem formulation process. Management objectives are by definition closely related to the assessment endpoints evaluated in ecological risk assessment, and it should be possible to characterize them using the measures described below.

Assessment Endpoints

According to EPA's *Guidelines for Ecological Risk Assessment*,[1] an assessment endpoint is an explicit expression of the environmental value that is to be protected, and is operationally defined by an ecological entity and its attributes. For example, a particular area has air toxics releases that may be affecting area salmon populations that are important for location recreation and commercial fishermen as well as an important resource for a local Native American tribe. In the study area, the salmon population is the valued ecological entity; reproduction and age class structure of a salmon population are some of their most important attributes. An appropriate assessment endpoint for this study area might be stated as *salmon reproduction and age class structure*. The ecological risk assessment for this study area would be structured to evaluate whether this specific salmon population is at risk from air toxics with regard to healthy reproductive ability and age class structure.

Given the diversity of species and other ecological attributes in almost any study area, the assessors generally establish at least one assessment endpoint that will, together, provide an assessment of air toxics impacts on the ecosystem as a whole. More than one assessment endpoint may be necessary at the ecosystem level.

23.3.2 Identifying The Participants

The participants for the ecological risk assessment may include some of the same people as those for the human health multipathway risk assessment (e.g., multimedia modelers that understand how to model for both human and ecological receptors). However,

- Additional risk managers may be involved, including natural resource management agencies such as the U.S. Fish and Wildlife Service; state, local, or tribal (S/L/T) fish and game departments; and/or private-sector risk managers.

- The risk assessment technical team will need significantly different experts (e.g., aquatic ecologists, experienced ecological risk assessors).

- The specific set of interested or affected parties may change or be expanded (e.g., different environmental groups may be more concerned/involved; local fishermen may become interested).

EPA's Public Involvement Policy may be helpful in performing this task (see http://www.epa.gov/stakeholders/policy2003/index.htm). Part V of this document provides additional information on community involvement.

23.3.3 Determining the Scope of the Risk Assessment

The scope of the human health multipathway risk assessment may expand to include additional exposure pathways and exposure routes, and to address ecological receptors of concern.

- The specific chemicals that will be the focus of the ecological risk assessment will generally be those that persist, bioaccumulate, and biomagnify (the PB-HAP compounds); however, a different set of PB-HAP compounds may be of more concern for the ecological risk assessment than for human health risk assessment. As with human health risk assessment, additional compounds may need to be added to the analysis, depending on study-area specific considerations.

- The specific sources included in the analysis may be focused on the subset that releases most or all of the identified COPECs.

- The physical boundaries of the study area may need to expand to include geographic areas where COPECs may be transported after deposition (e.g., the COPECs may have the potential to be deposited in a watershed and be carried out of the geographic area defined for the human health multipathway modeling).

23.3.4 Study-Specific Conceptual Model

A study-specific conceptual model for the ecological risk assessment is developed using the fundamental elements of the conceptual model developed for the human health multipathway assessment as a starting point. Steps to develop the study-specific ecological risk conceptual model include the following:

- Determine whether the set of potential sources and chemicals that were identified in the human health multimedia risk assessment are appropriate for the ecological risk assessment.

- Consider expanding the set of potential sources, chemicals, and exposure pathways to include those identified below (potential exposure pathways are listed in Exhibit 23-3).

- Identify ecological receptors of concern (see Section 23.3.4.1).

- Formulate a **risk hypothesis** that describes possible relationships between emissions of a chemical, exposure, and assessment endpoint response, including the information that sets the problem in perspective, as well as an identification of the proposed relationships that need evaluation.

- Identify assessment endpoints and measures of effects (See Section 23.3.4.2).

Exhibit 23-3. Common Exposure Pathways Considered for Ecological Air Toxics Risk Assessments
Direct exposure pathways: air → soil → soil-dwelling biota air → soil → water → aquatic biota air → water → aquatic biota air → water → sediment → aquatic biota air → soil → water → sediment → aquatic biota air → vegetation
Indirect exposure pathways: air → vegetation → bird/mammal air → soil → vegetation → bird/mammal air → soil → water → aquatic biota → fish air → soil → water → aquatic biota → fish → bird/mammal air → water → aquatic biota → fish air → water → aquatic biota → fish → bird/mammal air → soil → water → sediment → aquatic biota → fish air → soil → water → sediment → aquatic biota → fish → bird/mammal

Conceptual model diagrams, such as the example illustrated in Exhibit 23-4, are used (along with the risk hypothesis) to select the pathways to be evaluated in the analysis phase of the ecological risk assessment, as well as to assist in communication with risk managers.

As with human health risk assessments, the conceptual model for an ecological risk assessment must provide both a graphical representation of the important exposure pathways that are presumed to be occurring along with a written description that outlines each element of the conceptual model. Taken together, these two parts of the conceptual model clearly identify the sources of concern, the COPECs that will be evaluated, the exposure pathways, and the assessment endpoints. Similar to conceptual models for human health analysis, the conceptual model may be modified (perhaps a number of times) as more is learned about the study area.

23.3.4.1 Identifying Receptors of Concern

Ecological receptors of concern are an important part of the conceptual model. These may be plants, animals, habitats, communities, or larger ecosystem elements. Specific receptors may be of concern for a variety of reasons, including:

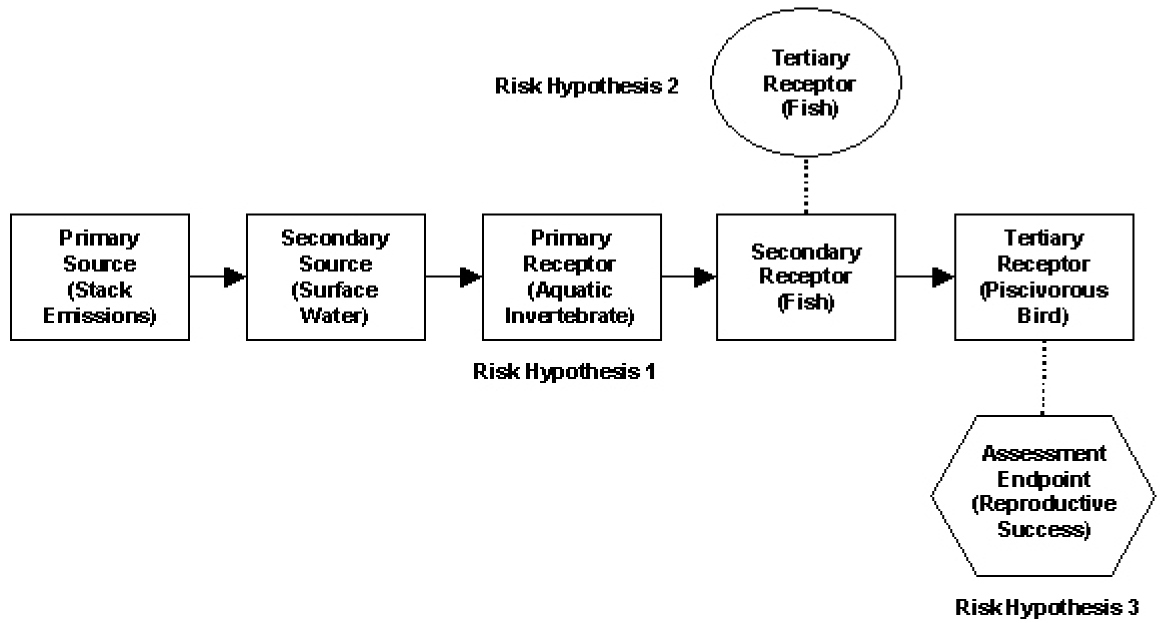
- The receptor (or one of it's life stages) is particularly vulnerable or sensitive to one or more COPECs;

- The receptor (usually a species or a community such as a wetland) is listed as endangered or threatened or is otherwise given special legal protection by the state or federal government;

- The receptor plays an important part in the overall structure or function of the ecological community or ecosystem;

- The receptor is of particular economic or cultural value to stakeholders.

Exhibit 23-4. Conceptual Model Diagram for Exposure of Piscivorous Birds to Air Toxics



Conceptual model diagrams are used, along with the risk hypothesis, to select the pathways to be evaluated in the analysis phase of the ecological risk assessment, as well as to assist in communication with risk managers. The three risk hypotheses in this hypothetical example are:

- **Risk Hypothesis 1**: Concentrations of chemical X in the surface water column are less than a level known to cause adverse effects on survival and reproduction in *Daphnia*
  - Mechanism: Chemical X causes mortality and inhibits larval development

- **Risk Hypothesis 2**: Dietary intake levels of chemical X in lake trout are less than a level known to cause adverse effects on reproductive ability
  - Mechanism: Due to a lack of enzyme A in lake trout, chemical X rapidly accumulates in lipid tissues and damages reproductive organs

- **Risk Hypothesis 3**: Dietary intake levels of chemical X in kingfisher chicks (passed to them by their parents) is less than a level known to adversely affect their survival
  - Mechanism: Chemical X accumulating in egg lipids is a metabolic toxin to the developing embryo

For taxonomic, physiological, and exposure reasons, it is important to consider a broad range of potential ecological receptors during problem formulation. For example, the types of adverse effects that may occur to terrestrial plant communities (e.g., impacts to photosynthesis, nitrogen fixation, nutrient uptake; foliar damage) are very different than the types of adverse effects that may occur to terrestrial mammals. Many ecological receptors (e.g., molds, lichens, many invertebrates) have unique physiological and biochemical features that may make them particularly sensitive to air toxics. Sensitive life stages often are a particular concern. In surface waters and sediments, early life stages (e.g., eggs, larvae) may be particularly sensitive to contaminants due to their small size (e.g., contaminants may readily penetrate cell membranes) and developmental processes (e.g., major metamorphosis from one life stage to another). Many terrestrial organisms (e.g., amphibians, dragonflies) have aquatic-dwelling early life stages. In addition, many invertebrates that can bioaccumulate PB-HAPs (e.g., aquatic dwelling dragonfly larvae) may be sources of food for sensitive life stages of other species (e.g., nestling birds). Often it is important to understand the aquatic and terrestrial food webs in the habitats of concern because these can be important parts of ecological exposure pathways. Top predators are often of special concern for exposure to PB-HAP compounds.

Ecological receptors for each habitat potentially impacted should be identified to ensure (1) plant and animal communities representative of the habitat are represented by the habitat-specific food web, and (2) potentially complete exposure pathways are identified. Screening-level ecological assessments often focus on the most sensitive organisms within an ecosystem or on the most sensitive life stages within a species, if these are known. Ecological receptor identification may need to include species both known and expected to be present in a specific habitat being evaluated, and include resident and migratory populations. Consultation with ecological experts is recommended. Potential sources of information include:

- **Government Organizations**. The U.S. Fish and Wildlife Service has biologists and other ecological experts and also maintains National Wetland Inventory maps.[7] State Natural Heritage Programs provide maps or lists of species based on geographic location, and are very helpful in identifying threatened or endangered species or areas of special concern.

- **Private or Local Organizations**. Private or professional organizations that are examples of sources of information include: National Audubon Society, the Nature Conservancy, local wildlife clubs, and universities.

- **General Literature**. Monographs, field guides, and other literature describing the flora and fauna of America and/or a particular region or state may be useful sources of information.

23.3.4.2 Identifying Assessment Endpoints and Measures of Effects

As previously noted, an **assessment endpoint** is an explicit expression of the environmental value that is to be protected or is of concern. It includes the identification of the ecological entity for the analysis (e.g., a species, ecological resource, habitat type, or community) as well as the attribute of that entity that is potentially at risk and important to protect (e.g., reproductive success, production per unit area, surface area coverage, biodiversity). The **measures of effects** are the measures used to assess these endpoints.[8]

Generally, a manageable subset of the most important assessment endpoints is selected for the risk assessment, and specific measures of effects that address each assessment endpoint are identified. EPA guidance documents discuss additional issues that are important in the identification of assessment endpoints.[9]

Appropriate selection of relevant assessment endpoints is critical so that the risk assessment provides valuable information for the associated risk management decisions. Assessment endpoints that can be measured directly are most effective, although assessment endpoints that cannot be measured directly, but can be represented by measures that are easily monitored or modeled, may also be used. Additional uncertainty is introduced depending on the relationship between the measurement and the assessment endpoints. Exhibit 23-5 provides examples of assessment endpoints, measures of effect, and other elements of the problem formulation phase.

EPA has recently released guidance that describes a set of endpoints, known as Generic Ecological Assessment Endpoints (GEAE), that can be considered and adapted for specific ecological risk assessments.[9] The entities and properties comprising the initial set of GEAEs is presented in Exhibit 23-6. The EPA Guidance defines GEAE further and provides the basis for the terms *assessment community* and *assessment population*, which are used in the definitions. In addition, EPA's Science Advisory Board recently published a *Framework for Assessing and Reporting on Ecological Condition*,[10] which includes a checklist of ecological attributes that should be considered when conducting ecological risk assessments and developing ecological management objectives (Exhibit 23-7). Note that many of these GEAEs and attributes focus at levels of ecological organization higher than organisms (e.g., species richness) or on ecological processes (e.g., nutrient cycling) rather than attributes of organisms (e.g., growth, reproduction).

It often is useful to summarize the results of the problem formulation process in a **problem formulation summary** that lists management objectives, assessment endpoints, and the structure of the risk assessment from exposure scenarios through risk characterization. Exhibit 23-8 provides an example problem formulation summary.

23.3.5 Analysis Plan and Quality Assurance Program Plan (QAPP)

As noted in Parts II and III of this reference manual, the Analysis Plan and QAPP are formulated by considering both the the conceptual model and the data quality required for the risk management decision. The Analysis Plan and QAPP, including data quality objectives, are just as important for the ecological risk assessment as they are for the human health risk assessment, and in some cases may be more complex. The analysis plan for the ecological risk assessment will need to match each of the elements of the conceptual model with the analytical approach that will be used to develop data about the element, including: sources; exposed populations and exposure pathways; exposure concentrations of COPEC; exposure conditions; toxicity of COPECs; risk characterization; QA/QC; documentation; roles and responsibilities; resources; and schedule.

Because the focus is on ecological receptors, additional types of monitoring (sampling and analysis) may need to be conducted. For example, it may be important to measure concentrations of COPECs in the sediments of surface water bodies as part of the analysis of direct exposures for sediment-dwelling invertebrates as well as bioaccumulation from these invertebrates to predatory fish through the aquatic food web.

Exhibit 23-5. Example of Ecological Risk Assessment Problem Formulation: EPA's Water Quality Criteria

A specific example of elements of the problem formulation step in a national-level ecological risk assessment can be found in the development of Ambient Water Quality Criteria by EPA's Office of Water pursuant to the Clean Water Act (CWA).[11] Water quality criteria have been developed for the protection of aquatic life from chemical stressors. The following elements of problem formulation support subsequent analyses in the risk assessments used to establish specific criteria.

Regulatory Goal

- CWA Section 101: Protect the chemical, physical, and biological integrity of the Nation's water.

Program Management Decisions

- Protect 99 percent of individuals in 95 percent of the species in aquatic communities from acute and chronic effects resulting from exposure to a chemical stressor.

Assessment Endpoints

- Survival of fish, aquatic invertebrates, and algal species under acute exposure
- Survival, growth, and reproduction of fish, aquatic invertebrates, and algal species under chronic exposure

Measures of Effect

- Laboratory LC_{50}s for at least eight species meeting certain requirements
- Chronic no-observed-adverse-effect-levels (NOAELs) for at least three species meeting certain requirements

Measures of Ecosystem and Receptor Characteristics

- Water hardness (for some metals)
- pH

The water quality criterion is a TRV derived from a distributional analysis of single-species toxicity data. It is assumed that the species tested (which represent a range of taxonomic groups) adequately represent the composition and sensitivities of species in a natural community.

Exhibit 23-6. Generic Ecological Assessment Endpoints[a]		
Entity	**Attribute**	**Identified EPA Precedents**
Organism-level endpoints		
Organisms (in an assessment population or community)	Kills (mass mortality, conspicuous mortality)	Vertebrates
	Gross anomalies	Vertebrates, shellfish, plants
	Survival, fecundity, growth	**Endangered species, migratory birds, marine mammals, bald and golden eagles**, vertebrates, invertebrates, plants
Population-level endpoints		
Assessment population	Extirpation	Vertebrates
	Abundance	Vertebrates, shellfish
	Production	Vertebrates (game/resource species), harvested plants
Community and ecosystem-level endpoints		
Assessment communities, assemblages, and ecosystems	Taxa richness	Aquatic communities, **coral reefs**
	Abundance	Aquatic communities
	Production	Plant assemblages
	Area	**Wetlands, coral reefs**, endangered/rare ecosystems
	Function	**Wetlands**
	Physical structure	Aquatic ecosystems
Officially designated endpoints		
Critical habitat for endangered or threatened species	Area Quality	
Special places	Ecological properties that relate to the special or legally protected properties	e.g., **National Parks, National Wildlife Refuges, Great Lakes**

[a]Generic ecological assessment endpoints for which EPA has identified existing policies and precedents (in particular, the specific entities listed in the third column). Bold indicates protection by federal statute.
Source: EPA's *Generic Ecological Assessment Endpoints (GEAE) for Ecological Risk Assessment*[9]

Exhibit 23-7. Essential Ecological Attributes and Reporting Categories

Landscape Condition
- Extent of ecological system/habitat types
- Landscape composition
- Landscape pattern and structure

Biotic Condition
- Ecosystems and communities
  - Community extent
  - Community composition
  - Trophic structure
  - Community dynamics
  - Physical structure
- Species and populations
  - Population size
  - Genetic diversity
  - Population structure
  - Population dynamics
  - Habitat suitability
- Organism condition
  - Physiological status
  - Symptoms of disease or trauma
  - Signs of disease

Chemical and Physical Characteristics (Water, Air, Soil, and Sediment)
- Nutrient concentrations
  - Nitrogen
  - Phosphorus
  - Other nutrients
- Trace inorganic and organic chemicals
  - Metals
  - Other trace elements
  - Organic compounds
- Other chemical parameters
  - pH
  - Dissolved oxygen
  - Salinity
  - Organic matter
  - Other
- Physical parameters

Ecological Processes
- Energy flow
  - Primary production
  - Net ecosystem production
  - Growth efficiency
- Material flow
  - Organic carbon cycling
  - Nitrogen and phosphorus cycling
  - Other nutrient cycling

Hydrology and Geomporphology

- Surface and groundwater flows
  - Pattern of surface flows
  - Hydrodynamics
  - Pattern of groundwater flow
  - Salinity patterns
  - Water storage
- Dynamic structural characteristics
  - Channel/shoreline morphology, complexity
  - Distribution/extent of connected floodplain
  - Aquatic physical habitat complexity
- Sediment and material transport
  - Sediment supply/movement
  - Particle size distribution patterns
  - Other material flux

Natural Disturbance Regimes
- Frequency
- Intensity
- Extent
- Duration

Source: U.S. EPA. 2002. *A Framework for Assessing and Reporting on Ecological Condition*[10]

Exhibit 23-8. Example Problem Formulation Summary

1. **Management Objective**
   - Bald eagle (entity), local population size (attribute), should be stable (desired state)

2. **Assessment Endpoints**
   - Bald eagle (entity), reproduction (measurable attribute)
   - Bald eagle (entity), chick survival (measurable attribute)

3. **Exposure Scenario**
   - Sediment –> pore water –> benthic invertebtrates –> forage fish –> bald eagle

4. **Risk Hypothesis**
   - Dose of chemical X to adult bald eagles from consumption of fish is less than a level known to cause adverse effects on reproductive ability
     - Mechanism: Chemical X damages reproductive organs (or interferes with egg shell development)
   - Dose of chemical X to bald eagle chicks (passed to them by their parents) is less than a level known to adversely affect their survival
     - Mechanism: Chemical X accumulating in egg lipids is a metabolic toxin to the developing embryo

5. **Metrics of Exposure**
   - Concentration of chemical X in fish
   - Dose of chemical X received through consumption of fish

6. **Measure of Effect**
   - TRV for chemical X (NOAEL or LOAEL) where adult reproduction was an endpoint
   - TRV for chemical X (NOAEL or LOAEL) where chick survival (mortality) was and endpoint

7. **Measure of Characteristics**
   - Proximity of bald eagle nest site to potentially contaminated foraging areas
   - Proximity of alternative (non-contaminated) foraging areas to the nest site

8. **Risk Characterization**
   - HQ = Oral Intake of chemical X/TRV (separate calculations for adults and chicks)

23.4 Tiered Ecological Risk Assessments

One of the key elements in the ecological risk assessment process is deciding if and when further analysis is warranted. As with human health risk assessment, EPA recommends a tiered approach to ecological risk assessment.[1] Each of these tiers follows the basic three steps (problem formulation, analysis, and risk characterization) but with varying levels of complexity in the assessment and with varying requirements for resources. Examples of the three tiers of ecological risk assessment approaches are described briefly below.

- **Screening-Level** ecological risk assessments provide a general indication of the *potential* for ecological risk (or lack thereof) and may be conducted for several purposes including: (1) to prioritize COPECs based on their relative environmental behavior (e.g., relative potential for bioaccumulation or to exhibit chronic toxicity) or determine their relative contribution to the overall risk estimate; (2) to estimate the likelihood that a particular ecological risk exists; (3) to identify the need for additional data collection efforts; or (4) to focus more detailed ecological risk assessments where warranted. Screening assessments often use simplified conservative assumptions in place of detailed modeling. For example, concentrations in aquatic invertebrates or fish might be estimated from the modeled or measured water concentrations (obtained as part of a multipathway human health risk assessment) and available bioconcentration factors (BCFs) or bioaccumulation factors (BAFs). Another example is the comparison of maximum sediment and water concentrations to screening level TRVs. A screening level assessment, while abbreviated, is nonetheless a complete risk assessment. Therefore, each assessment should include documentation supporting the risk characterization and uncertainty analysis. Some examples of screening level TRVs used in screening level ecological risk assessments are available from EPA's draft Ecological Soil Screening Level Guidance (http://www.epa.gov/superfund/programs/risk/ecorisk/guidance.pdf) and EPA Region 4 (http://www.epa.gov/region4/waste/ots/ecolbul.htm).

- **More Refined** assessments are generally used to: (1) identify and characterize the current and potential threats to the environment from an air toxics release; (2) evaluate the ecological impacts of alternative emissions control or abatement policies; and (3) establish emissions levels that will protect those natural resources at risk. A more refined assessment may contain a more intensive evaluation than a screening level assessment, and usually employs multipathway analysis to estimate if, and to what extent, ecological receptors (e.g., an oyster fishery, a wild duck population, or a unique wetland community) may be exposed. The exposure and potential impact are characterized and evaluated against predetermined assessment endpoints (i.e., edibility of oysters, sustainability of the duck population, maintenance of the integrity of the wetland community). This tier may be iterative. For example, a multipathway analysis using conservative assumptions may first be performed to identify whether any of the COPECs emitted from the sources in an area pose a potentially significant concern to one or more ecological receptors. If so, a more detailed multipathway risk assessment, using more site-specific data, may be performed. From this last stage a detailed characterization of the environmental risks is developed.

- **Probabilistic** assessments are used to increase the strength of the *predictive* evaluation of ecological risks, as well as help better evaluate distributions of observational data for an ecological risk assessment. Screening-level and more refined assessments usually utilize simplified point estimates in the development of a risk characterization, while the probabilistic tier of assessment uses probability distributions as inputs. Therefore, this tier generally can yield risk estimates that allow for a more complete characterization of variability and uncertainty. Although probabilistic assessments generally are resource-intensive, they may be especially valuable in situations when the risks are close to a policy threshold or if the management decisions, if implemented, would require significant expenditures.

Additional Reference Materials

EPA has developed extensive technical and policy guidance on how ecological risk assessments should be planned and performed. These are available at EPA's "Tools for Ecological Risk Assessment" website http://www.epa.gov/superfund/programs/risk/tooleco.htm.

- EPA's *Guidelines for Ecological Risk Assessment*, April 1998. This document expands upon and replaces the earlier 1992 *Framework for Ecological Risk Assessment.*

- EPA's *Ecological Risk Assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments, Interim Final*, June 1997. This document includes processes and steps for use in ecological risk assessments at Superfund sites. This document supersedes the 1989 *RAGS, Volume II, Environmental Evaluation Manual, Interim Final*. Supplements to ERAGS include the *Eco Updates* (Intermittent Bulletin Series, 1991 to present), which provide brief recommendations on common issues for Superfund ecological risk assessments. The approaches and methods outlined in the *Guidelines* and in *ERAGS* are generally consistent with each other.

- *Risk Assessment Guidance for Superfund (RAGS): Volume 1–Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments)*, June 2001. This guidance specifies formats that are required to present data and results in baseline risk assessments at Superfund sites; many of these formats are useful for air toxics ecological risk assessments.

- Policy Memorandum: *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, F. Henry Habicht, Deputy Administrator, Feb. 26, 1992. This policy requires baseline risk assessments to present ranges of risks based on "central tendency" and "high-end" exposures with corresponding risk estimates.

- Policy Memorandum: *Role of the Ecological Risk Assessment in the Baseline Risk Assessment*, Elliott Laws, Assistant Administrator, August 12, 1994. This policy requires the same high level of effort and quality for ecological risk assessments as commonly performed for human health risk assessments at Superfund sites.

- Policy Memorandum: *EPA Risk Characterization Program*, Carol Browner, Administrator, March 21, 1995. This policy clarifies the presentation of hazards and uncertainty in human health and ecological risk assessments, calling for clarity, transparency, reasonableness, and consistency.

- *Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites*. Stephen D. Luftig for Larry D. Reed, October 7, 1999. This document presents six key principles in ecological risk management and decision-making at Superfund sites; these principles are also useful for air toxics ecological risk assessments.

References

1. U.S. Environmental Protection Agency. 1998. *Guidelines for Ecological Risk Assessment*. Risk Assessment Forum, Washington, D.C., April 1998. EPA/630/R095/002F. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460.

2. U.S. Environmental Protection Agency. 1999. *Residual Risk Report to Congress*. EPA-453/R-99-001. Available at: http://www.epa.gov/ttn/oarpg/t3/reports/risk_rep.pdf.

3. U.S. Environmental Protection Agency. 1995. *Ecological Risk and Decision Making Workshop.* December 1995. EPA 230/B96/004B.

4. Moore, D.W.J., et al. 1999. A probabilistic risk assessment of the effects of methylmercury and PCBs on mink and kingfishers along East Fork Poplar Creek, Oak Ridge, Tennessee, USA. *Environmental Toxicology and Chemistry* 8:2941-2953.

5. Suter II, G.W., et al. 2000. *Ecological Risk Assessment of Contaminated Sites*. Lewis Publishers, Boca Raton, FL. (see pages 228-231).

6. U.S. Environmental Protection Agency. 2001. *Planning for Ecological Risk Assessment: Developing Management Objectives (External Review Draft).* Risk Assessment Forum, Washington, D.C., June 2001. EPA/630/R01/001A. Available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20683

7. U.S. Fish and Wildlife Service. 2003. National Wetlands Inventory Maps. Available at: http://nwi.fws.gov.

8. U.S. Environmental Protection Agency. 1992. *Framework for Ecological Risk Assessment*. Risk Assessment Forum, Washington, D.C., February 1992. EPA/630/R92/001.

9. U.S. Environmental Protection Agency. 2003. *Generic Ecological Assessment Endpoints (GEAE) for Ecological Risk Assessment.* Risk Assessment Forum, Washington, D.C., October 2003. Available at: http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=55131.

10. U.S. Environmental Protection Agency. 2002. *A Framework for Assessing and Reporting on Ecological Condition*. Science Advisory Board, Washington, D.C., September 2002. EPA-SAB-EPEC-02-009A. Available at: http://www.epa.gov/sab/pdf/epec02009a.pdf.

11. U.S. Environmental Protection Agency. 1985. *Guidelines for Deriving Natural Numerical Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses*. Office of Water Regulations and Standards, Washington, D.C. EPA/822/R85/100. Available at: http://yosemite.epa.gov/water/owrccatalog.nsf/0/3fab714d53e9ae5385256b0600723bd3?OpenDocument